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Quality Metrics and Risk Management with High Risk Radiation Oncology Procedures
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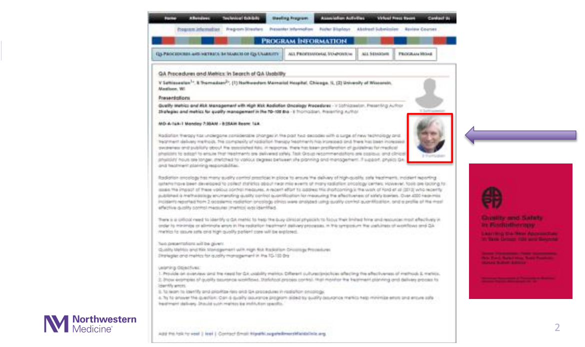
AAPM 2014 Symposium on QA Procedures and Metrics:
In Search of a QA Usability Metric
July 21, 2014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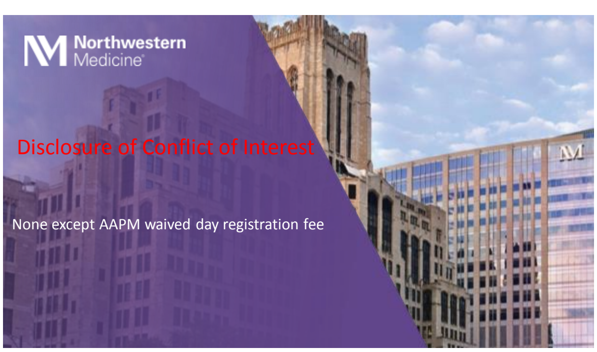
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Disclosure of Conflict of Interest
None except AAPM waived day registration fee

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Topics

Introduction
AAPM Summer School 2013
Review of Northwestern Data
Risk Categories or Scales
Examples of High Risk Procedure Catastrophic Failures
Time Out as a QA Usability Metric for High Risk Procedures
Conclusions

Learning Objectives

- Provide an overview and the need for QA usability metrics: Different cultures/practices affecting the effectiveness of methods & metrics.
- Show examples of quality assurance workflows, Statistical process control, that monitor the treatment planning and delivery process to identify errors.
- To learn to identify and prioritize risks and QA procedures in radiation oncology.
- Try to answer the question: Can a quality assurance program aided by quality assurance metrics help minimize errors and ensure safe treatment delivery?
- Should such metrics be institution specific?

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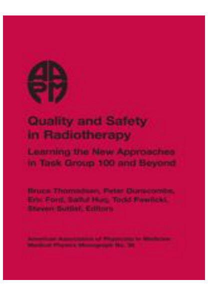

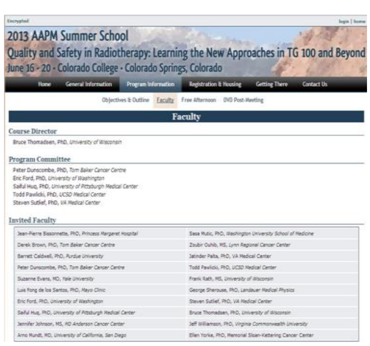

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2013 AAPM Summer School
Quality and Safety in Radiotherapy: Learning the New Approaches in TG 100 and Beyond
June 16 - 20 · Colorado College · Colorado Springs, Colorado

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Objectives & Outline | Faculty | Free Afternoon | DVD Post-Meeting

Faculty

Course Director

Bruce Thomadsen, PhD, *University of Wisconsin*

Program Committee

Peter Dunscombe, PhD, *Tom Baker Cancer Centre*
Eric Ford, PhD, *University of Washington*
Saiful Huq, PhD, *University of Pittsburgh Medical Center*
Todd Pawlicki, PhD, *UCSD Medical Center*
Steven Sutlief, PhD, *VA Medical Center*

Invited Faculty

Jean-Pierre Bissonnette, PhD, *Princess Margaret Hospital*	Sasa Mutic, PhD, *Washington University School of Medicine*
Derek Brown, PhD, *Tom Baker Cancer Centre*	Zoubir Ouhib, MS, *Lynn Regional Cancer Center*
Barrett Caldwell, PhD, *Purdue University*	Jatinder Palta, PhD, VA Medical Center
Peter Dunscombe, PhD, *Tom Baker Cancer Centre*	Todd Pawlicki, PhD, *UCSD Medical Center*
Suzanne Evans, MD, *Yale University*	Frank Rath, MS, *University of Wisconsin*
Luis Fong de los Santos, PhD, *Mayo Clinic*	George Sherouse, PhD, *Landauer Medical Physics*
Eric Ford, PhD, *University of Washington*	Steven Sutlief, PhD, *VA Medical Center*
Saiful Huq, PhD, *University of Pittsburgh Medical Center*	Bruce Thomadsen, PhD, *University of Wisconsin*
Jennifer Johnson, MS, *MD Anderson Cancer Center*	Jeff Williamson, PhD, *Virginia Commonwealth University*
Arno Mundt, MD, *University of California, San Diego*	Ellen Yorke, PhD, Memorial Sloan-Kettering Cancer Center

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AAPM Summer School 2013

- A discussion of TG–100's efforts was a central feature of the summer school.
- Optimizing the care pathway, a.k.a. the process map, is another opportunity for enhancing not only quality and safety, but also efficiency.
- Some relevant techniques were discussed throughout the summer school

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- **In all the stages of radiotherapy there is potential to cause a major harm to the patient**
- **Physicists play an important role in identifying and minimizing these risks**

Ch. 1: Introduction to Quality 11

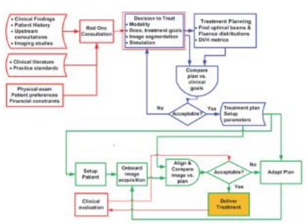

Figure 1–2. Overview of the radiation therapy process adapted to include image-guidance. The upper left, upper right, and bottom boxes and pathways denote physician-dominated subprocesses (clinical assessment, evaluation, and prescription), physics-dominated subprocesses (planning), and treatment delivery subprocesses, respectively. (Refer to the CD for the color version of this figure.)

Device-centric vs Process-centric Quality Management

- Traditionally, the radiation oncology physics community has had a largely device-centric perspective.
- This has changed in recent years with the recognition that many of the safety and quality issues have significant human factors content.
- The AAPM's Task Group 100 is working to bring objectivity to quality management programs, covering both equipment and people, with the example being IMRT (Huq et al. 2008).

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Financial Reality & Time Commitment

- It is worth placing the proposed interventions and measures in the context of the financial reality of today's health care.
- While a full-blown FMEA or root cause analysis (RCA) could be expensive to perform, it is not hard to devise shortcuts and expedited approaches, e.g., do a simple analysis on your own without a team, which will bring benefits.
- The first hurdle is to develop a familiarity and comfort level with these error management techniques that are foreign to most of us.
- Recent documents, such as "Safety is No Accident," suggest measures for enhancing safety and quality that have minimal resource requirements (Zietman, Palta, and Steinberg 2012).
- For example, "no interruption zones," which are widely considered to be effective, require some leadership but little else.

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Early Efforts & Emerging Developments in Process-centric Quality Management

- The first major efforts to systematically address error mitigation in a radiation therapy process were AAPM's guidance documents for clinical brachytherapy published in the late 1990s.
- The 1997 TG–56 report *Code of Practice for Brachytherapy Physics* (Nath et al. 1997) laid out a detailed process-centered QA approach for temporary low dose-rate brachytherapy procedures using "2-D" treatment planning.
- Meanwhile, the 1998 TG–59 Report *High dose-rate brachytherapy treatment delivery* (Kubo et al. 1998) serves as an extended example of applying TG–56 principles to the HDR brachytherapy domain.

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TG 56 & TG 59 – Early Pioneers

- Both reports accepted that low-probability human errors—including measurement errors, communication failures, and transcription errors—must be detected and corrected to avoid catastrophic treatment delivery errors.
- This approach was designed to complement the prescriptive QA program outlined by TG 56 for HDR and LDR brachytherapy devices.
- These reports attempted to lay out a general QM system design process that could be adapted to many different kinds of clinical procedures.
- Reports 56 and 59 proposed that the QA program was not a separate activity imposed upon the clinical workflow, but that such processes should be prospectively designed from the ground up with the goal of making them robust to error propagation by building QC and QA checks into their basic structure.

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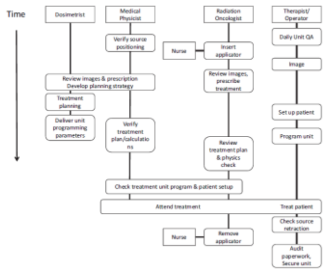
Figure 1–5. TG–59 process flow diagram of the one-physicist HDR brachytherapy workflow model.



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QA Areas of Focus in Radiation Oncology

- Machine QA
- Process QA
- Focus on Daily Treatment Delivery
- Adequate focus on commissioning

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QA Procedures

- QA procedures are needed to ensure equipment are functioning according to acceptable tolerances
- Also needed are procedures and workflow to ensure accurate planning & delivery of treatments
- Physicists play an important role in both of these steps

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Quality Matters
FISCAL YEAR 2013
Northwestern Memorial and Northwestern Lake Forest hospitals are committed to creating the safest environment for patients.
As the centers of inpatient care for the Northwestern Medicine health system, our hospitals offer patients the comfort of knowing that they will benefit from our focus on quality and service. Our hospitals were recognized in the 2013 ranking of the nation's "Best Hospitals" by U.S. News & World Report. Additionally, both hospitals earned an "A" Safety Score for the second consecutive year from The Leapfrog Group, which provides the only national public comparisons of hospitals regarding safety and quality. These markers of excellence speak to our dedication to providing exceptional care.
Effective:
Safe:
Patient and Family Centered:
To learn more about our hospitals' quality performance on more than 300 measures, we invite you to view our quality results at nmh.org and lfh.org.
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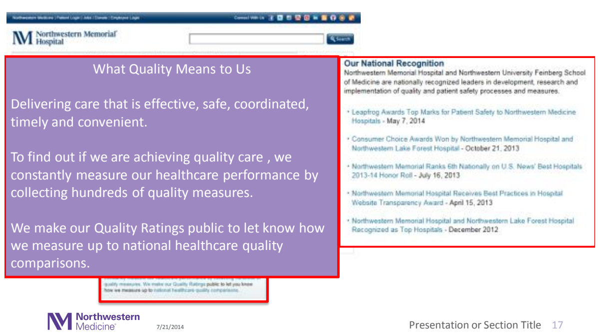
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What Quality Means to Us
Delivering care that is effective, safe, coordinated, timely and convenient.
To find out if we are achieving quality care , we constantly measure our healthcare performance by collecting hundreds of quality measures.
We make our Quality Ratings public to let know how we measure up to national healthcare quality comparisons.
Our National Recognition
Northwestern Memorial Hospital and Northwestern University Feinberg School of Medicine are nationally recognized leaders in development, research and implementation of quality and patient safety processes and measures.
• Leapfrog Awards Top Marks for Patient Safety to Northwestern Medicine Hospitals - May 7, 2014
• Consumer Choice Awards Won by Northwestern Memorial Hospital and Northwestern Lake Forest Hospital - October 21, 2013
• Northwestern Memorial Ranks 6th Nationally on U.S. News' Best Hospitals 2013-14 Honor Roll - July 16, 2013
• Northwestern Memorial Hospital Receives Best Practices in Hospital Website Transparency Award - April 15, 2013
• Northwestern Memorial Hospital and Northwestern Lake Forest Hospital Recognized as Top Hospitals - December 2012
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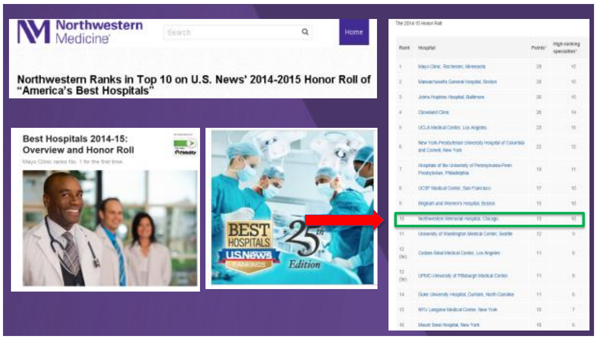
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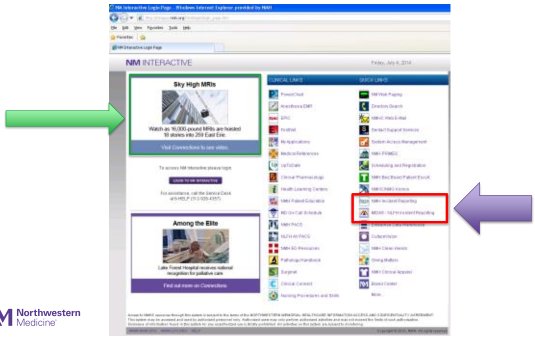

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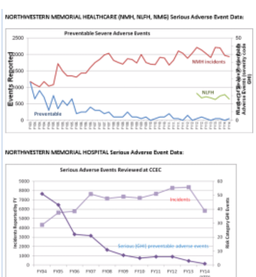
NMH Incident Reporting System



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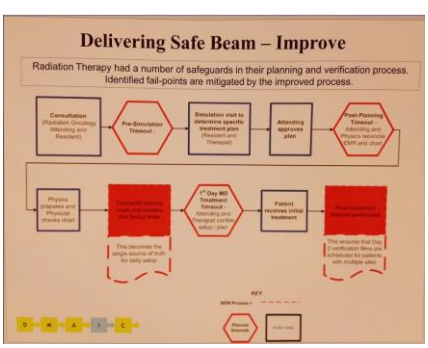

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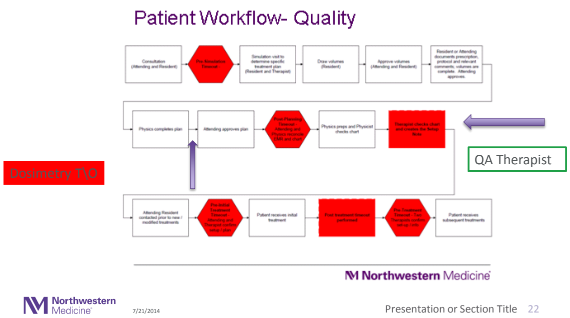

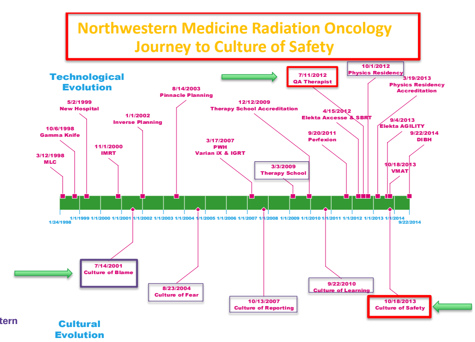

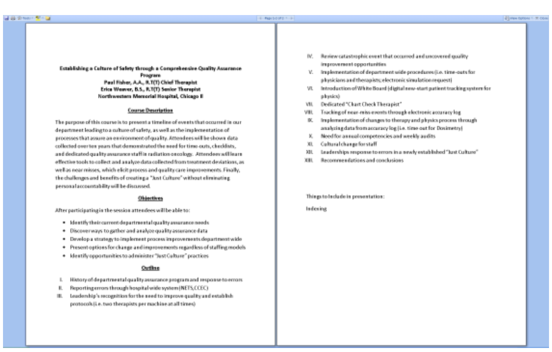

Establishing a Culture of Safety through a Comprehensive Quality Assurance Program
Paul Fisher, A.A., R.T(T) Chief Therapist
Erica Weaver, B.S., R.T(T) Senior Therapist
Northwestern Memorial Hospital, Chicago Il

Course Description

The purpose of this course is to present a timeline of events that occurred in our department leading to a culture of safety, as well as the implementation of processes that assure an environment of quality. Attendees will be shown data collected over ten years that demonstrated the need for time-outs, checklists, and dedicated quality assurance staff in radiation oncology. Attendees will learn effective tools to collect and analyze data collected from treatment deviations, as well as near misses, which elicit process and quality care improvements. Finally, the challenges and benefits of creating a "Just Culture" without eliminating personal accountability will be discussed.

Objectives

After participating in the session attendees will be able to:

- Identify their current departmental quality assurance needs
- Discover ways to gather and analyze quality assurance data
- Develop a strategy to implement process improvements department wide
- Present options for change and improvements regardless of staffing models
- Identify opportunities to administer "Just Culture" practices

Outline

I. History of departmental quality assurance program and response to errors
II. Reporting errors through hospital wide system (NETS,CCEC)
III. Leadership's recognition for the need to improve quality and establish protocols (i.e. two therapists per machine at all times)
IV. Review catastrophic event that occurred and uncovered quality improvement opportunities
V. Implementation of department wide procedures (i.e. time-outs for physicians and therapists; electronic simulation request)
VI. Introduction of White Board (digital new-start patient tracking system for physics)
VII. Dedicated "Chart Check Therapist"
VIII. Tracking of near-miss events through electronic accuracy log
IX. Implementation of changes to therapy and physics process through analyzing data from accuracy log (i.e. time out for Dosimetry)
X. Need for annual competencies and weekly audits
XI. Cultural change for staff
XII. Leaderships response to errors in a newly established "Just Culture"
XIII. Recommendations and conclusions

Things to Include in presentation:

Indexing

Good Catch Award

Jeff, Julie and Anna were recognized at this month's M&M conference for a great catch they were responsible for last month.

In May, Julie was performing a daily, routine Cone-Beam CT scan on a patient prior to the patient's radiation treatment. This scan is generally only used for iso-center verification and not used for diagnostic purposes. However, Julie noticed that the patient's lungs appeared hazy with mediastinal changes. Julie, along with Jeff Levinson and Anna Pecherczyk, brought this to the attention of the attending physician. After reviewing the image, the patient was immediately sent for an X-ray, follow-up CT, and bronchoscopy where a mucus plug was identified. The patient was then sent for surgery.

Margaret, the program manager from Patient Safety and Quality Strategies stated that this was "one of the "best" good catches that Patient Safety has seen in a while". Great job Julie, Jeff and Anna! Our patients are so lucky to have such an amazing team taking care of them each and every day. Thank you for going above and beyond to care for the patients we treat. This is truly an example of "Everything Matters"!

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The Profession

A Comprehensive Quality Assurance Program for Personnel and Procedures in Radiation Oncology: Value of Voluntary Error Reporting and Checklists

John A. Kalapurakal, MD,* Aleksandar Zafirovski, MBA, RT,* Jeffery Smith, BS,* Paul Fisher, AS, RT,* Vythialingam Sathiaseelan, PhD,* Cynthia Barnard, MBA, MSJS, CPHQ,[‡] Alfred W. Rademaker, PhD,[†] Nick Rave, MS,[§] and Bharat B. Mittal, MD*

*Departments of *Radiation Oncology and [†]Preventive Medicine, Northwestern University Feinberg School of Medicine, and Departments of [‡]Quality Strategies and [§]Physicians Services, Northwestern Memorial Hospital, Chicago, Illinois*

Received Nov 8, 2012, and in revised form Jan 21, 2013. Accepted for publication Feb 2, 2013

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Workflow and Quality Checks

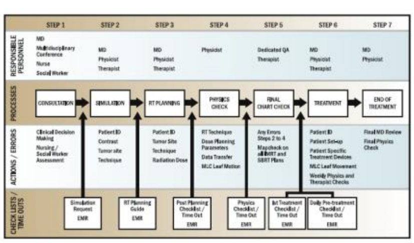

Fig. 1. Radiation oncology departmental personnel and procedures, key functions, potential errors, and position of checklists and timeouts where handoffs occur between different teams. EMR = electronic medical records; ID = identification; MD = physician; MLC = multileaf collimator; QA = quality assurance; RT = radiation therapy.

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Key Components of Our Safety Program

- Time outs
- Checklists

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Timeouts and Checklists


Post-Planning Checklist / Timeout — Y N
- EMR Prescription, Target Volumes, Pathology, Imaging
- Correct Patient in all systems?
- Is the Diagnosis in EMR correct?
- Is the Treatment Site correct?
- Simulation Note Approved?
- Treatment Note Approved?
- Staff Present (initials)

First Treatment Checklist / Timeout — Y N
- Correct Patient on Treatment Table
- Treatment Consent present and complete
- Digitally Reconstructed Radiographs (DRRs) match Portal Images
- Staff Present (initials)

Daily Radiation Treatment Checklist / Timeout — Y N
- Identify Patient
- Name / Date of birth / Photo
- Treatment Side / Site
- Treatment Devices
- Isocenter with Read Back
- All Marks Set
- Table Height Reminder


Initial Physics Review Checklist / Time Out — Y N
- Patient Setup Information Review
- Site is Correct and Identical
- Name of Area of Treatment is Correct
- Treatment Technique Review
- Patient Prescription and Treatment Plan Review
- Other
- Treatment Plan Review by Secondary Check
- Approved By

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Time Out as a Quality Metric for High Risk Procedures

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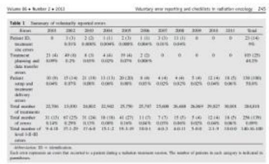
From: Spruce & Ogg, Prevention of Wrong Site Surgery

Time Outs



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Radiation Oncology High Risk Procedures

- External beam therapy => IMRT
- Brachytherapy => HDR & LDR
- Radiosurgery
- SBRT
- SART
- IORT

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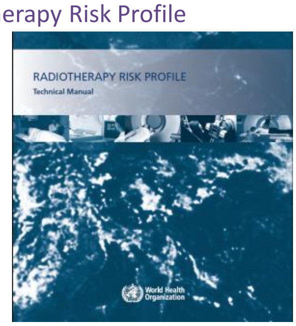
Radiotherapy Risk Profile

- Through published literature review identified risk areas in the radiotherapy treatment process
- Specifically targeted interventions to improve patient safety



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Potential Risk Areas in Radiotherapy Treatment

Table 1: Potential risk areas (•) in radiotherapy treatment

Stages	Patient factors: History	Patient factors: Clinical examination	Patient factors: Pathology	Equipment system factors	Staff factors: Communication	Staff factors: Guidelines/protocol	Staff factors: Training	Staff factors: No. of staff	Suggested preventive measures
Assessment of patient & decision to treat	•	•	•		•	•	•	•	Peer review process Evidence-based practice
Prescribing treatment protocol		•	•		•	•	•		Peer review process Standard protocol Competency certification Consultation with seniors
Positioning & immobilization	•	•		•	•	•	•	•	Competency certification QA check & feedback Incident monitoring
Simulation & imaging				•	•	•	•	•	Competency certification QA check & feedback Incident monitoring
Planning				•	•	•	•	•	QA check & feedback New staff & equipment orientation Competency certification Incident monitoring
Treatment information transfer				•	•	•	•	•	Clear documentation Treatment sheet check 'Record & verify' system In-vivo dosimetry
Patient setup	•	•	•	•	•	•	•	•	Competency certification Incident monitoring Supervisor audit
Treatment delivery	•	•	•	•	•	•	•	•	Incident monitoring Imaging/Portal film In-vivo dosimetry
Treatment review		•	•	•	•	•	•	•	Competency certification Incident monitoring Independent audit

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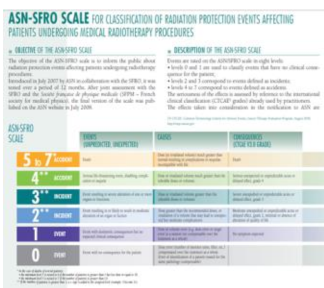
French Risk Scale

- Important to Categorize Near Miss Events using a Risk Scale
- Helps in identifying and minimizing major risks that can lead to catastrophic failures


ASN-SFRO SCALE FOR CLASSIFICATION OF RADIATION PROTECTION EVENTS AFFECTING PATIENTS UNDERGOING MEDICAL RADIOTHERAPY PROCEDURES

OBJECTIVE OF THE ASN-SFRO SCALE

The objective of the ASN-SFRO scale is to inform the public about radiation protection events affecting patients undergoing radiotherapy procedures.
Introduced in July 2007 by ASN in collaboration with the SFRO, it was tested over a period of 12 months. After joint assessment with the SFRO and the Société française de physique médicale (SFPM – French society for medical physics), the final version of the scale was published on the ASN website in July 2008.

DESCRIPTION OF THE ASN-SFRO SCALE

Events are rated on the ASN/SFRO scale in eight levels:
- levels 0 and 1 are used to classify events that have no clinical consequence for the patient;
- levels 2 and 3 correspond to events defined as incidents;
- levels 4 to 7 correspond to events defined as accidents.

The seriousness of the effects is assessed by reference to the international clinical classification (CTCAE grades) already used by practitioners.
The effects taken into consideration in the notification to ASN are

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Definition of Quality Metrics

- The Business Dictionary defines the word metrics as "standards of measurement by which efficiency, performance, progress, or Quality of a plan, process, or product can be assessed."
- Quality metrics is applied to measuring whether or not a given process will produce products and services that meet quality standards.


What sorts of metrics assess quality improvement?

A quality metric allows a user to quantify the quality of a selected aspect of care by comparing it to a criterion. There are different types of quality metrics:

- Access measure - assesses the patient's ability to obtain timely and appropriate health care.
- Outcome measure - is the patient's health status after receiving health care services. It can be used to evaluate the quality of care to the extent that health care services influence the likelihood of desired health outcomes.
- Patient experience measure - aggregates reports of patients about their observations of and participation in health care.
- Process measure - assesses the actual health care service provided to, or on behalf of, a patient.
- Structure measure - describes a feature of a health care organization or clinician relevant to its capacity to provide health care (e.g., nurse to patient ratio, number of beds).

In addition, the cost of care, efficiency of care and value of care are measures that can inform decision-makers regarding performance. Each metric helps provide a more complete picture of the health care quality status of an organization.

Resources:

- AQA Parameters for Selecting Measures for Physician Performance (PDF - 30KB)
- National Quality Measures Clearinghouse
- AMA Physician Consortium for Performance Improvement Measures

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Examples of Quality Metrics & Effectiveness

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Clinical Investigation: Quality Assurance

Quality Control Quantification (QCQ): A Tool to Measure the Value of Quality Control Checks in Radiation Oncology

Eric C. Ford, PhD,* Stephanie Terezakis, MD,* Annette Souranis,* Kendra Harris, MD,* Hiram Gay, MD,† and Sasa Mutic, PhD†

*Department of Radiation Oncology and Molecular Radiation Sciences, Johns Hopkins University, Baltimore, Maryland; and †Department of Radiation Oncology, Washington University, St. Louis, Missouri

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Summary

Radiation oncology has many quality control practices in place to ensure the delivery of high-quality, safe treatments. Tools are lacking, however, to assess the impact of these various control measures. This report presents a methodology—quality control quantification—for measuring the effectiveness of safety barriers. Over 4000 near-miss incidents reported from 2 academic radiation oncology clinics were analyzed using quality control quantification, and a profile of the most effective quality control measures was established.

The combination of checks with highest effectiveness (from 15 common QC checks) includes:

=> physics plan review
=> physician plan review
=> EPID based in vivo portal dosimetry
=> radiation therapist timeout
=> weekly physics chart check
=> the use of checklists
=> port films
=> SSD distance checks

Conclusions: The effectiveness of QC measures in radiation oncology depends sensitively on which checks are used and in which combinations. A small percentage of errors cannot be detected by any of the standard formal QC checks currently in broad use, suggesting that further improvements are needed. These data require confirmation with a broader incident-reporting database. © 2012 Elsevier Inc.

Examples of High Risk Procedure Catastrophic Failures

- HDR
- Linac Radiosurgery
- Gamma Knife Radiosurgery
- LDR Prostate Brachytherapy
- EBRT => IMRT & SBRT

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Practical Radiation Oncology (2012) 2, 157–163

pro

www.practicalradonc.org

Original Report

A 2-year review of recent Nuclear Regulatory Commission events: What errors occur in the modern brachytherapy era?

Susan Richardson PhD*

Department of Radiation Oncology, Mallinckrodt Institute of Radiology, Washington University School of Medicine, St Louis, Missouri

Received 1 July 2011; revised 10 August 2011; accepted 23 August 2011

Abstract

Purpose: To perform a retrospective analysis of recently reported brachytherapy errors to the Nuclear Regulatory Commission and to compare with historical trends.

Methods: All events reported in the 2-year period from January 1, 2009 to December 31, 2010 were categorized and analyzed. The 4 main areas of dose delivery were Gamma Knife radiosurgery, therapeutic radiopharmaceutical administration, high-dose-rate brachytherapy, and low-dose-rate brachytherapy. The different types of errors were wrong site, wrong dose, unintended exposure, lost or leaking source, or other. The causes of events were specified as the following: communication errors, equipment malfunction, human error, lack of training, or miscellaneous.

Results: One hundred and forty-seven events were found in the 2-year period. This error reporting rate far surpasses previous reports. The greatest number of events reported was for low-dose-rate brachytherapy, and the most common cause of error was human error. Wrong dose was the error that occurred most often, followed by wrong site.

Conclusions: Very simple treatment errors, such as wrong patient, or wrong side of patient treated, are still occurring. Newer, complex deliveries such as high-dose-rate partial breast irradiation and low-dose-rate prostate brachytherapy also had a large number of events reported in this sampling. This report can help institutions establish needs for quality assessment and quality control processes.

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Practical Radiation Oncology: July-September 2012

Table 1 Summary of events reported from January 1, 2009 to December 31, 2010

Type of dose delivery (No. of events)	Type of error (No. of events)	Isotope (No. of events)
Gamma Knife (13)	Wrong site (7)	Co-60 (7)
	Wrong dose (5)	Co-60 (5)
	Unintended exposure (1)	Co-60 (1)
RP (34)	Wrong site (2)	I-125 (1) Y-90 (1)
	Wrong dose (22)	I-131 (9) Y-90 (13)
	Unintended exposure (8)	I-131 (8)
	Other (2)	P-32 (1) Y-90 (1)
HDR (33)	Wrong site (20)	Ir-192 (19) Y-90 (1)
	Wrong dose (9)	Ir-192 (5) Sr-90 (4)
	Unintended exposure (3)	Ir-192 (3)
	Other (1)	Ir-192 (1)
LDR (66)	Wrong site (6)	I-125 (3) Pd-103 (1) Cs-137 (2)
	Wrong dose (45)	I-125 (37) Pd-103 (4) Cs-131 (3) Variable (1)
	Lost or leaking source (13)	I-125 (9) Cs-137 (4)
	Unintended exposure (1)	Cs-137 (1)
	Other (1)	Cs-131 (1)
Unspecified (1)	Other (1)	Unspecified (1)

Left-hand column describes type of dose delivery employed when the error occurred. Middle column describes the nature of the event. Right-hand column shows the isotopes that were used during the event. Numbers in parentheses indicate the number of events reported. GK, Gamma Knife; HDR, high dose rate; LDR, low dose rate; RP, radiopharmaceutical.

Table 2 Causes of events (left) and type of dose delivery involved with the event (right)

Causes of event (No. of events)	Type of dose delivery (No. of events)
Communication issues (10)	LDR (3) RP (7)
Equipment malfunction (23)	GK(6) HDR (8) LDR (4) RPI (5)
Human error (97)	GK(7) HDR (20) LDR (58) RP (12)
Lack of training (12)	HDR (1) LDR (5) RP (6)
	Other (1)
Miscellaneous (5)	Other (5)

Numbers in parentheses indicate the number of events reported. GK, Gamma Knife; HDR, high dose rate; LDR, low dose rate; RP, radiopharmaceutical.

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Medical Events in Brachytherapy

MEDICAL EVENTS IN BRACHYTHERAPY: WHAT HAVE WE LEARNED?

Wanbao Gao, PhD
Southern Advanced Med Physics, Inc.
Arlington, Texas

June 16-20, 2013
The 38th AAMD Annual Meeting
San Antonio, Texas

Medical Event (misadministration)

- Total delivered dose differs from the prescribed dose by 20% or more; or
- The delivered dose, in a single fraction, differs from the prescribed fractional dose by 50% or more; or
- Other MEs: excessive dose to normal tissue/skin, wrong patient, wrong site, wrong isotope, wrong modality, or use of leaking sources

10 CFR35.3045

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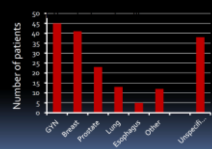
Medical Events in Brachytherapy

Medical events in HDR Brachytherapy (1999-2012)

- 150 ME reports to NRC/ states;
- 178 patients were involved;
- Majority of errors - targeting misses or wrong treatment sites: 117 (66%);
- The primary cause - use of incorrect lengths of TTs/catheters (in measurement, planning or treatment): 74(42%)

HDR ME – Applications



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Medical Events in Brachytherapy

Types of errors in HDR

- Targeting miss or wrong treatment site (117):
  incorrect length, step size, insertion, dislodgement;
- Treatment planning errors(29):
  Wrong dose, pres. point, activity, mag. factor;
- Treatment delivery errors (15):
  Wrong plan, dwell times, balloon deflation;
- Source retraction problems (22);
- Others (15)

MEs in Prostate Seed Implant (1999-2012)

- Total number of ME implants: 346 (127 VA)

Excluded: missing shipments, lost seeds, use of leaking sources, aborted procedures, or retracted events;

1. Incorrect source strength, incorrect dose rate constant, or other planning errors (32);
2. Needle/seed misplacement or excessive dose to normal tissue (104, 37 VA);
3. Discrepancy in dose to target(210, 90 VA):
   Principally D90 (200), mainly D90<80%
   Other parameters used: D100, D80, V100

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Never Events

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Time Out in Radiation Oncology

AbstractID: 12987 Title: Implementation of a "time out" procedure in radiation oncology: a multi-institution study over nine years results in a three-fold reduction in misadministrations

Purpose: In recent years the medical industry as a whole has put an increased emphasis on "Time Out or TO" procedures as a way to improve the quality of care. For radiation oncology, TO procedures are rarely used since the error (medical events, misadministrations) rate is estimated to be < 0.06% for reportable events. It is suggested that the error rates may be further reduced by implementing a TO for all radiation therapy procedures. The purpose of this study is to quantify the effectiveness of TO procedures in radiation therapy.

Method and Materials: The misadministration records from five different cancer centers in New York and Michigan States were reviewed from 2000 to 2009. Within this time period, a TO procedure was implemented at each cancer center. Error rates were tabulated for the years before and after the time out procedure was implemented. Errors were broken down into 2 categories: minor and major as defined by the following:

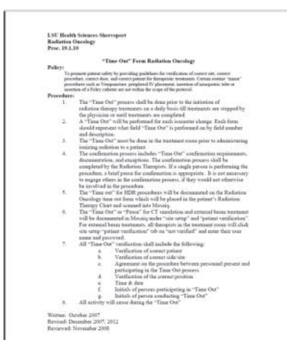
1) Minor discrepancy (error<10% in total dose; *issues resolved before major error occurred*)
2) Major Errors of which there are two types :
   a) Recordable Misadministration (error ≥ 10% but < 20%)
   b) Reportable Misadministration (error ≥ 50% in 1 day; error ≥ 20% in total, wrong site, person or energy)

Results: After the implementation of TO procedures, a reduction in error rates by a factor of three was realized. For the clinics in this study, the TO procedure was supported by administration as an extension of hospital policy for medical procedures.

Conclusion: TO procedures were found to be effective in reducing the number of errors in radiation therapy. Based on these findings, it is recommended that the TO be implemented in all radiation oncology centers: the improvements to patient safety easily justified the cost of an additional 15 seconds per field.

A reduction in error rates by a factor of three was realized

Rasmussen, B.; Chu, K. Medical Physics, 2010, vol. 37, issue 6, p. 3450



LSU Health Sciences Shreveport
Radiation Oncology
Proc. 19.1.10

"Time Out" Form Radiation Oncology

Policy:

To promote patient safety by providing guidelines for verification of correct site, correct procedure, correct dose, and correct patient for therapeutic treatments. Certain routine "minor" procedures such as Venipuncture, peripheral IV placement, insertion of nasogastric tube or insertion of a Foley catheter are not within the scope of the protocol.

Procedure:

1. The "Time Out" process shall be done prior to the initiation of radiation therapy treatments on a daily basis till treatments are stopped by the physician or until treatments are completed.
2. A "Time Out" will be performed for each isocenter change. Each form should represent what field "Time Out" is performed on by field number and description.
3. The "Time Out" must be done in the treatment room prior to administering ionizing radiation to a patient.
4. The confirmation process includes "Time Out" confirmation requirements, documentation, and exceptions. The confirmation process shall be completed by the Radiation Therapists. If a single person is performing the procedure, a brief pause for confirmation is appropriate. It is not necessary to engage others in the confirmation process, if they would not otherwise be involved in the procedure.
5. The "Time out" for HDR procedures will be documented on the Radiation Oncology time out form which will be placed in the patient's Radiation Therapy Chart and scanned into Mosaiq.
6. The "Time Out" or "Pause" for CT simulation and external beam treatment will be documented in Mosaiq under "site setup" and "patient verification". For external beam treatments, all therapists in the treatment room will click site setup "patient verification" tab on "not verified" and enter their user name and password.
7. All "Time Out" verification shall include the following:
   a. Verification of correct patient
   b. Verification of correct side site
   c. Agreement on the procedure between personnel present and participating in the Time Out process
   d. Verification of the correct position
   e. Time & date
   f. Initials of persons participating in "Time Out"
   g. Initials of person conducting "Time Out"
8. All activity will cease during the "Time Out"

Written: October 2007
Revised: December 2007, 2012
Reviewed: November 2008

Gamma Knife Radiosurgery

- Correct plan transmitted
- Correct isodose chosen
- Correct treatment site\side => Trigeminal

External Beam Radiotherapy

- IMRT => open fields
- Wedge => missing

LDR Prostate Brachytherapy

- Correct activity for monotherapy vs boost
- Zero base image

LDR GYN Brachytherapy

- Correct activity for Cs sources in plan
- Sources loaded correctly

HDR Brachytherapy

- Correct cylinder

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January 1, 2012 to June 15, 2014

Procedure	No of Procedures	Medical Events	Near Miss Events
Gamma Knife	479	0	3
HDR Brachytherapy	157	0	1
LDR Brachytherapy - Prostate	15	0	1
LDR Brachytherapy - GYN	50	0	0
IORT	90	0	0
SBRT	502	0	3

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Barriers to Effective Time Outs

- Time constraints
- Staffing
- Culture
- Lack of communication
- Education\Training
- “Mindfulness” => Recognizing the risk
- Perception of importance

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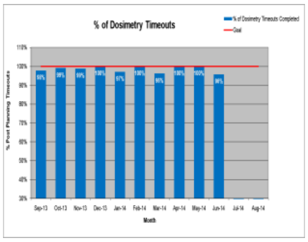
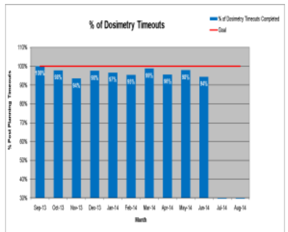
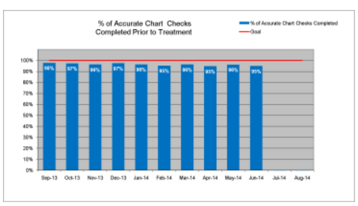
Dosimetry T\O Compliance



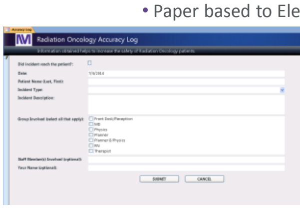


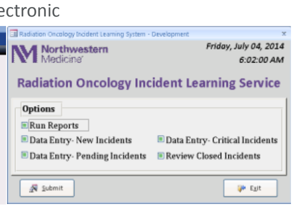
Accurate Charts



Incident Learning Systems

- Valuable for tracking near miss events
- Paper based to Electronic





Conclusions

- Time outs are good tools to mitigate catastrophic failures
- Identify key steps to check which can lead to catastrophic failures
- Quality of time outs is critical
- Developing a culture of safety is very important
- Audit to maintain quality
- Continuous communication between caregivers is essential

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Questions?

- Is Time Out a Quality Metric?
- How can we measure it?
- How can we use this simple tool as an effective Quality Metric to eliminate catastrophic errors in radiation oncology?

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